UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/541,354 | 06/21/2006 | Jorn Bullerdiek | 14677-007US | 1121 |

61263 7590 06/18/2008

PROSKAUER ROSE LLP
1001 PENNSYLVANIA AVE, N.W.,
SUITE 400 SOUTH
WASHINGTON, DC 20004

| EXAMINER | |
|---|---|
| SHEN, WU CHENG WINSTON | |
| ART UNIT | PAPER NUMBER |
| 1632 | |
| MAIL DATE | DELIVERY MODE |
| 06/18/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/541,354 | BULLERDIEK, JORN | |
| | Examiner | Art Unit | |
| | WU-CHENG Winston SHEN | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-91* is/are pending in the application.

4a) Of the above claim(s) *5-15,19-29,35-44,53-58,62,63,67-75,81-85 and 87-91* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-4,16-18,30-34,45-52,59-61,64-66,76-80,and 86.

**DETAILED ACTION**

1. Claims 5-15, 19-29, 35-44, 53-58, 62, 63, 67-75, 81-85, and 88-91 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and cannot depend from any other multiple dependent claims. See MPEP § 608.01(n). Accordingly, the claims 5-15, 19-29, 35-44, 53-58, 62, 63, 67-75, 81-85, and 87-91 are withdrawn and have not been included in this restriction. Amendments of these claims may lead to further restriction.

Claims 1-4 and 45-52 are "use claims" and these claims are interpreted as "a method of using". Amendments of these claims inconsistent with this interpretation may be subject to further restriction.

Claims 1-4, 16-18, 30-34, 45-52, 59-61, 64-66, 76-80, and 86 are subject to restriction in this office action.

***Election/Restrictions***

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1 and 3, drawn to a method of using the *transcription product(s)* thereof one or several nucleic acid(s) in a process, whereby the process is selected from the group comprising angiogenesis, neovascularization, transmyocardial revascularization, wound healing, angiogenesis following wounding, epithelialization and healing of tooth and bone implants, whereby the nucleic acid(s) is/are one(s) that code(s) for high mobility group (HMG) proteins, including HMGB 1 or a part thereof.

II. Claims 1 and 3, drawn to a method of using the *translation product(s)* thereof one or several nucleic acid(s) in a process, whereby the process is selected from the group comprising angiogenesis, neovascularization, transmyocardial revascularization, wound healing, angiogenesis following wounding, epithelialization and healing of tooth and bone implants, whereby the nucleic acid(s) is/are one(s) that code(s) for high mobility group (HMG) proteins, including HMGB 1 or a part thereof.

III. Claims 2 and 4, drawn to a method of using the *transcription product(s)* thereof one or several nucleic acid(s) for the manufacture of a medicament for the prevention and/or treatment of a disease, whereby the disease is selected from the group which is related to lacking or excessive angiogenesis or neovascularization or wound healing, or requires transmyocardial revascularization, whereby the nucleic acid is one that codes for high mobility group (HMG) proteins, including HMGB 1 or a part thereof.

IV. Claims 2 and 4, drawn to a method of using the *translation product(s)* thereof one or several nucleic acid(s) for the manufacture of a medicament for the prevention and/or treatment of a disease, whereby the disease is selected from the group which is related to lacking or excessive angiogenesis or neovascularization or wound healing, or requires transmyocardial revascularization, whereby the nucleic acid is one that codes for high mobility group (HMG) proteins, including HMGB 1 or a part thereof.

V. Claims 16-18, drawn to a method for affecting angiogenesis or neovascularization or wound healing of a tissue comprising the following steps: a) providing a tissue or a part thereof, b) adding *transcription product(s)* of one or several nucleic acid(s), and c) incubating the tissue with the transcription product(s) of nucleic acid(s), whereby the nucleic acid(s) is/are selected from the group comprising the genes for the high mobility group proteins, and, optionally, d) obtaining or recovering the tissue or an intermediate thereof.

VI. Claims 16-18, drawn to a method for affecting angiogenesis or neovascularization or wound healing of a tissue comprising the following steps: a) providing a tissue or a part thereof, b) adding *translation product(s)* of one or several nucleic acid(s), and c) incubating the tissue with the transcription product(s) of nucleic acid(s), whereby the nucleic acid(s) is/are selected from the group comprising the genes for the high mobility group proteins, and, optionally, d) obtaining or recovering the tissue or an intermediate thereof.

VII. Claims 30, 34, 76 and 80, drawn to a method for the screening of a compound for promoting and/or inhibiting a process, comprising the following steps: a) providing a test system for the process; b) providing a candidate compound; and c) testing the candidate compound and determining the reaction caused by the candidate compound in the test system.

VIII. Claims 31, 34, 77 and 80, drawn to a method for the screening of a compound for promoting and/or inhibiting a process, comprising the following steps: a) providing a test system for the process; b) providing a reference compound; c) testing the reference compound in the test system and determining the reaction caused by the reference compound in the test system; d) providing a candidate compound; e) testing the candidate compound in the test system and determining the reaction caused by the candidate compound in the test system; and f) comparing the reaction of the reference compound in the test system to the reaction of the candidate compound in the test system.

IX. Claims 32, 34, 78, and 80, drawn to a method for the screening of a compound for the promotion and/or inhibition of a process, comprising the following steps: a) providing a test system for the process; b) providing a reference compound, whereby the reference compound has a marker; c) testing the reference compound in the test system and determining the reaction caused by the reference compound in the test system; d) providing the candidate compound; and e) testing the candidate compound in the test system, whereby the test system comprises the reference compound, and determining the reaction of the test system, whereby the

amount of released reference compound and/or released marker of the reference compound is determined.

X. Claims 33, 79, and 80, drawn to a method for the screening of a compound for the promotion and/or inhibition of a process, whereby the process is selected from the group comprising angiogenesis, neovascularization, transmyocardial vascularization and wound healing, comprising the following steps: a) providing a test system for the process; b) providing a candidate compound, whereby the candidate compound has a marker; c) testing the candidate compound in the test system and determining the reaction caused by the candidate compound in the test system; d) providing a reference compound; and e) testing the reference compound in a test system, whereby the test system comprises a candidate compound, and determining the reaction of the test system, whereby the amount of released candidate compound and/or of released marker of the candidate compound is determined.

XI. Claims 45 and 52, drawn to a method of using the *transcription product* of a nucleic acid for a process, whereby the process is selected from the group comprising tissue regeneration, repair of DNA damages, wound healing, cell mobility, angiogenesis in the wound area, epithelialization, tissue aging, prevention of tissue aging, rejuvenation of tissue, vascularization alter cardiac infarction and healing of tooth and bone implants, whereby the nucleic acid is selected from the group comprising genes for basic DNA binding proteins.

XII. Claims 45 and 52, drawn to a method of using the *translation product* of a nucleic acid for a process, whereby the process is selected from the group comprising tissue regeneration, repair of DNA damages, wound healing, cell mobility, angiogenesis in the wound area, epithelialization, tissue aging, prevention of tissue aging, rejuvenation of tissue, vascularization alter cardiac infarction and healing of tooth and bone implants, whereby the nucleic acid is selected from the group comprising genes for basic DNA binding proteins.

XIII. Claims 46 and 52, drawn to a method of using the *transcription product* of a nucleic acid, thereof and/or the translation product thereof for a process, whereby the process is selected from the group comprising dedifferentiation of cells and re-programming of cells, for tissue build-up and/or tissue regeneration, in particular based on dedifferentiation and/or differentiation of the tissue to be build up or to be regenerated, whereby the nucleic acid is selected from the group comprising genes for basic DNA binding proteins.

XIV. Claims 46 and 52, drawn to a method of using the *translation product* of a nucleic acid, thereof and/or the translation product thereof for a process, whereby the process is selected from the group comprising dedifferentiation of cells and re-programming of cells, for tissue build-up and/or tissue regeneration, in particular based on dedifferentiation and/or differentiation of the tissue to be build up or to be regenerated, whereby the nucleic acid is selected from the group comprising genes for basic DNA binding proteins.

XV. Claims 47 and 52, drawn to a method of using the *transcription product* of a nucleic acid, for the manufacture of a medicament for prevention and/or treatment of a disease, whereby the disease is selected from the group comprising diseases which require the repair DNA damages, diseases which require tissue regeneration, diseases which require wound healing, diseases which go along with tissue aging, diseases which require tooth and bone implants, diseases which go along with tissue aging, wound healing disorders, skin diseases, xeroderma pigmentosum, leather skin, skin cancer, skin cancer after bum, skin aging after burn, burn and cardiac infarction, whereby the nucleic acid is selected from the group comprising genes for basic DNA-binding proteins.

XVI. Claims 47 and 52, drawn to a method of using the *translation product* of a nucleic acid, for the manufacture of a medicament for prevention and/or treatment of a disease, whereby the disease is selected from the group comprising diseases which require the repair DNA damages, diseases which require tissue regeneration, diseases which require wound healing, diseases which go along with tissue aging, diseases which require tooth and bone implants, diseases which go along with tissue aging, wound healing disorders, skin diseases, xeroderma pigmentosum, leather skin, skin cancer, skin cancer after bum, skin aging after burn, burn and cardiac infarction, whereby the nucleic acid is selected from the group comprising genes for basic DNA-binding proteins.

XVII. Claims 48 and 52, drawn to a method of using the *transcription product* of a nucleic acid, for the manufacture of a cosmetic product, preferably a cosmetic

product for tissue regeneration, wound healing, prevention of leather skin, prevention of skin cancer, in particular skin cancer after sun burn, skin aging, in particular skin aging after sun burn, tissue aging inhibition and/or tissue juvenation, whereby the nucleic acid is selected from the group comprising genes for basic DNA-binding proteins.

XVIII. Claims 48 and 52, drawn to a method of using the *translation product* of a nucleic acid, for the manufacture of a cosmetic product, preferably a cosmetic product for tissue regeneration, wound healing, prevention of leather skin, prevention of skin cancer, in particular skin cancer after sun burn, skin aging, in particular skin aging after sun burn, tissue aging inhibition and/or tissue juvenation, whereby the nucleic acid is selected from the group comprising genes for basic DNA-binding proteins.

XIX. Claims 49-51 and 52, drawn to a method of using the *transcription product* of a nucleic acid for the manufacture of a medicament for the prevention and/or treatment of a disease, whereby the disease is selected from the group comprising skin diseases, xeroderma pigmentosum, leather skin, skin cancer, skin cancer after sun burn, sun burn, acute wounds and chronic wounds, whereby the nucleic acid is selected from the group comprising genes for basic DNA-binding proteins.

XX. Claims 49-51 and 52, drawn to a method of using the *translation product* of a nucleic acid for the manufacture of a medicament for the prevention and/or treatment of a disease, whereby the disease is selected from the group comprising skin diseases, xeroderma pigmentosum, leather skin, skin cancer, skin cancer after

sun burn, sun burn, acute wounds and chronic wounds, whereby the nucleic acid is selected from the group comprising genes for basic DNA-binding proteins.

XXI. Claims 59-61, drawn to a method for the regeneration of tissue comprising the following steps: a) providing a tissue or a part thereof, b) adding the *transcription product* of a nucleic acid, and c) incubating the tissue and the transcription product of nucleic acid, whereby the nucleic acid is selected from the group comprising genes for basic DNA-binding proteins, and, optionally, d) obtaining or recovering the regenerated tissue or a intermediate form thereof.

XXII. Claims 59-61, drawn to a method for the regeneration of tissue comprising the following steps: a) providing a tissue or a part thereof, b) adding the *translation product* of a nucleic acid, and c) incubating the tissue and the translation product of nucleic acid, whereby the nucleic acid is selected from the group comprising genes for basic DNA-binding proteins, and, optionally, d) obtaining or recovering the regenerated tissue or a intermediate form thereof.

XXIII. Claims 64-66, drawn to a method for the dedifferentiation and/or reprogramming of cells comprising the following steps: a) providing one or several cells, b) adding the *transcription product* of a nucleic acid, and c) incubating the cell and the transcription product of the nucleic acid, whereby the nucleic acid is selected from the group comprising genes for basic DNA-binding proteins.

XXIV. Claims 64-66, drawn to a method for the dedifferentiation and/or reprogramming of cells comprising the following steps: a) providing one or several cells, b) adding the *translation product* of a nucleic acid, and c) incubating the cell and

the translation product of the nucleic acid, whereby the nucleic acid is selected from the group comprising genes for basic DNA-binding proteins.

XXV. Claim 86, drawn to a sun protection agent comprising at least the *transcription product* of a nucleic acid, whereby the nucleic acid is selected from the group comprising genes for basic DNA-binding proteins.

XXVI. Claim 86, drawn to a sun protection agent comprising at least the *translation product* of a nucleic acid, whereby the nucleic acid is selected from the group comprising genes for basic DNA-binding proteins.

3. The inventions listed as Groups I-XXVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Unity of invention between different categories of inventions will only be found to exist if the specific combinations of inventions are present. Those combinations include:

1) A product and a special process of manufacture of said product.

2) A product and a process of use of said product.

3) A product, a special process of manufacture of said product, and a process of use of said product.

4) A process and an apparatus specially designed to carry out said process.

5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant application, see MPEP § 1850. Groups I-XXIV represent different methods requiring different starting products and different method steps to practice the method. Group XXV and Group XXVI represent different products with distinct material compositions and uses.

Applicant's claims encompass multiple inventions, multiple products and multiple methods, and do not have a special technical feature which link the inventions one to the other, and lack unity of invention. There is no common special technical feature among all the groups. The common technical feature encompassed in Groups I-IV is a nucleic acid encoding a high mobility group (HMG) protein. The common technical feature encompassed in Groups V-VI and XI-XXVI is a nucleic acid. The common technical feature encompassed in Groups VII-X is a compound affecting a process.

).

4. Additionally, **further restriction** is required for Groups I-XIV to elect a single process among distinct processes including angiogenesis, neovascularization, transmyocardial revascularization, wound healing, angiogenesis following wounding, epithelialization and healing of tooth and bone implants, because these processes are different physiological processes performing distinct physiological functions. If Applicant elects any of Groups I-XIV, an election of a disease set forth above is required.

Additionally, **further restriction** is required for Groups XV-XX to elect a single disease (or a single physiological condition) including the diseases which require the repair DNA

damages, diseases which require tissue regeneration, diseases which require wound healing, diseases which go along with tissue aging, diseases which require tooth and bone implants, diseases which go along with tissue aging, wound healing disorders, skin diseases, xeroderma pigmentosum, leather skin, skin cancer, skin cancer after burn, skin aging after burn, burn and cardiac infarction, because these diseases are caused by distinct underlying mechanisms and treated by therapeutic approaches. If Applicant elects any of Groups XV-XX, an election of a disease set forth above is required.

5. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction were not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Wu-Cheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-273-3157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the supervisory patent examiner, Peter Paras, can be reached on (571) 272-4517. The fax number for TC 1600 is (571) 273-8300.

Formatted: Line spacing: single

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Wu-Cheng Winston Shen, Ph. D.
Patent Examiner
Art Unit 1632

/Valarie Bertoglio/
Primary Examiner, Art Unit 1632